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K964307

**LUNAR**

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## 9.0 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92(c).

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**Date:** October 28, 1996

**Device/Trade Name:** Expanded Reference Values for  
DPX Series Bone Densitometer

**Common Name:** Bone Densitometer

**Classification Name:** Bone Densitometer  
21CFR 892.1170

**Predicate Device:** K89021 Modified DPX Bone Densitometer

## 9.1 DESCRIPTION OF THE DEVICE:

The expanded reference BMD values described in the present submission include both male and female data from white adults in the U.S. and northern Europe. These new reference values are for BMD measurements taken at the AP Spine, Lateral Spine, Proximal Femur, Total Body and Radius Shaft sites. Male data for lateral spine BMD measurements are not available. The Operator's Manual contains tabulated summaries of these updated reference values and citations to published sources of these materials.

### 9.3 CONCLUSION

The expanded reference BMD values incorporated in this submission merely add to the reference value data already established and provided with the DPX series bone densitometers. These data can be used for comparative purposes by the clinician entirely at his/her discretion. No new safety and effectiveness questions are raised with the inclusion of these expanded reference values.

  
*Signed*

Kenneth D. Buroker  
*Printed Name*

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*Title*